

REMARKS

The specification was objected to because English system measurements were used.

The specification has been amended to show Metric units followed by the equivalent English units.

Claims 12-27 were rejected as being obvious and unpatentable over Cornish et al.

The Patent Office stated that Cornish et al. disclosed a guidewire comprising a titanium alloy core wire. However Cornish et al. does not disclose a titanium alloy core wire. The Cornish et al. patent only mentions a nickel alloy, nickel titanium. The only other metal mentioned by name in the Cornish et al. patent is stainless steel.

The Patent Office also stated that Cornish et al. discloses a guidewire being formed of "stainless steel or nickel titanium alloy or a combination thereof, but can also consist of any material that yields the approximate mechanical properties of the named metals so long as the material is sufficiently biocompatible." and that therefore it is obvious to use a titanium molybdenum alloy guidewire since it is biocompatible and has the approximate mechanical properties of stainless steel and nickel titanium.

The Patent Office asserts that the applicant acknowledges that the titanium molybdenum alloy as claimed has the approximate properties of stainless steel and nickel titanium.

First the Patent Office cites the broad statement from Cornish et al. that stainless steel or nickel titanium or other materials with the approximate properties can be used as a guidewire. The Patent Office does not say what properties are being referred to nor does the Cornish et al. patent. The Patent Office is using broad undefined generalities to show that the claims are obvious. The properties are never defined and the range of properties to make them approximate are never defined. Then the examiner states the applicant acknowledges that the known titanium alloy has the approximate mechanical properties of stainless steel and nickel titanium.

The patent office is taking the applicant's statements out of context. The applicant first made a broad statement that the titanium alloy had properties between that of stainless steel and nickel titanium and then went on to talk about what those properties were. The applicant also listed other properties of titanium molybdenum, which are different from stainless steel and nickel titanium.

The applicant stated that the titanium molybdenum alloy guidewire is less springy than the nickel titanium alloy guidewires and more springy than stainless steel guidewires and that the titanium molybdenum alloy guidewire is stiffer than the nickel titanium alloy guidewires and less stiff than stainless steel guidewires. These statements show that the titanium molybdenum alloy has properties between those of stainless steel and nickel titanium but does not give the range of the differences or show that they metals have approximately the same properties as the patent office states. The ranges of stiffness and springiness between the metals is quite large and makes a noticeable difference in the performance of the guidewires. The affidavit of Dr. Chambers who has tested and compared the stainless steel guidewires, the nickel titanium guidewires and the titanium molybdenum alloy guidewires says that the titanium molybdenum alloy guidewires have superior properties to stainless steel and nickel titanium guidewires.

Other properties of the titanium molybdenum guidewire are listed in the application.

The application at page 7 lines 4-6 states " The titanium molybdenum alloy can be deflected 42% more than stainless steel with no permanent deformation..." This shows a rather large deviation from stainless steel for this property. The application also states the titanium molybdenum alloy has a lower force deflection rate and a higher spring back and flexibility.

Another property of the guidewires being compared in the application (see page 8, lines 3-7) teaches that when nickel titanium (Nitinol) is deflected it returns to its original shape 100%, stainless steel returns to about 5% of its original shape and the titanium molybdenum alloy (Beta III) returns to about 50% of its original shape. Again these are vast differences in performance of these properties.

There is an array of other differences showing a wide gap in performance properties of titanium molybdenum alloy and nickel titanium and stainless steel. For example on page 9

line 18 of the application it states that the titanium molybdenum alloy guidewire steers better than stainless steel or titanium nickel alloy guidewires. Other features listed at page 6 lines 18 to 20 state "The titanium molybdenum alloy is easier to use and has better rotatability, softness and pushability for use in the passageways of patients than guidewires made of other materials. So the properties of ease of use, rotatability, softness and pushability are different enough to make the titanium molybdenum alloy guidewire noticeably easier to use and are therefore not approximately the same properties as stainless steel and nickel titanium guidewires.

The applicant stated that some of the stated properties were between that of stainless steel and nickel titanium but did not say how large the gaps were or that the properties were approximately the same. The Patent Office has taken broad statements out of context and has not shown that the properties of titanium molybdenum are approximately the same as stainless steel and nickel titanium.

The applicant has shown in the specification that many of the properties of the claimed titanium molybdenum alloy guidewire are very different from stainless steel or nickel titanium guidewires.

The patent office in citing Herms et al., in this office action, quote Herms et al. at column 6 line 3-5 which states that the titanium alloy (the titanium molybdenum alloy) has three times the elasticity of stainless steel, showing that the properties are not at all alike.

The applicant has not acknowledged that the titanium molybdenum alloy has the approximate properties of stainless steel guidewires or nickel titanium guidewires, nor has the patent office shown what properties are being compared, what the ranges of those properties are, or that the guidewires in question yield the same approximate mechanical properties. Therefore the obviousness rejection should be withdrawn and the claims should be allowed.

The broad statement made by the Patent Office that the properties of the guidewires are approximately the same are not substantiated. Therefore the Patent Office's rejection of

obviousness based on the broad statement in Cornish et al. is not a valid rejection. The Patent Office has failed to show the approximate properties which would make the claims obvious.

Further Dr. Chambers, in the affidavit attached, states that he has tested the titanium molybdenum guidewires and the properties of the titanium molybdenum alloy guidewire are superior to those of stainless steel or nickel titanium further showing that their properties are not approximately the same as the Patent Office contends.

The Patent Office position that a patent such as Cornish et al., which states stainless steel or nickel titanium or something else with similar properties, can be used in the core of a guidewire proscribes any discovery of other materials, which would be good guidewires because they would have to have similar properties and be biocompatible. This is clearly not a defensible position since a patent need merely make such broad statements to block all improvements in the art from being patentable.

For all of the above reasons the patent office rejection of the claims as being obvious over Cornish et al. should be withdrawn.

The Patent Office has rejected the application based on In Re Leshbin, 227 F.3d 197, 125 USPQ 416 (CCPA 1960) stating that the selection of a known material based on its suitability for the intended use is a design consideration within the skill of the art.

In this case there is no selection of a known material based on the suitability for the intended use reducing the selection of the material to a design consideration.

Leshbin was for a plastic container. He used a different plastic for the same purpose in the container. The substitute of plastics changed nothing about the container. It was merely a design choice and obvious. Here the selection of a totally different material for the guidewire makes a guidewire having different properties, it operates with different characteristics and is not merely a simple design choice. As Dr. Chambers's affidavit shows the performance of the guidewires is different, the guidewires can be more precisely controlled, they have better kink resistance, they are better able to negotiate tortuous routes in the blood vessels, they have good torque, and the new titanium molybdenum alloy reduces the need to replace guidewires during procedures. This is not a mere design choice for performing the same task as the patent office contends. Changing the material of the guidewire changes everything about the

guidewire, makes it a superior guidewire and according to Dr. Chambers it was not obvious to do so.

Therefore the rejection of the claims based on *In Re Leshbin* should be withdrawn.

The Patent Office also rejected the claims as being obvious over Cornish et al. in view of Mayer since Mayer is a medical device used in body passageways which uses the titanium molybdenum alloy as stated in applicant's claims. The Patent Office states that it would be obvious to combine the teachings of Cornish et al. and Mayer in order to avoid undue irritation to patients having sensitivity to nickel.

The patent office stated "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al to include a titanium molybdenum alloy as taught by Mayer in order to avoid undue irritation to patients having a sensitivity to nickel [0079]." This apparently was offered by the Patent Office to show an allergic sensitivity to nickel titanium guidewires. However the reference is to stents and refers to nickel sensitivity in Elgiloy alloy not nickel titanium and not in guidewires. Elgiloy is an alloy with 15.5 % Ni, 40.0% Co, 20.0% Cr, 7.0% Mo, 2% Mn, 0.150% C, 0.0100 % Be and the balance Fe. This does not show an allergic reaction to nickel from nickel titanium guidewires during guidewire procedures.

As further evidence that patients are allergic to guidewires containing nickel the Patent Office cited an article from the internet found at <http://www.dermnetnz.org/dna.nickel.alergy/info.html> titled "Nickel Allergy" where nickel or unnamed nickel alloys on the skin of patients was offered to show a problem of nickel allergies to nickel titanium alloys of guidewires used in blood vessels during guidewire procedures. The Patent Office has not shown that nickel titanium guidewires causes an allergic reaction in the blood vessels of patients during guidewire procedures. The patent office has only shown that some people are allergic to nickel and some unnamed nickel alloys on their skin. The patent office has not shown that a nickel titanium guidewire caused an allergic reaction in the blood vessels of patients during a guidewire procedure.

To counter the Patent Office's assertions that guidewires having nickel content cause allergic reactions in patients the applicant herewith provides the affidavit of Jeffery W.

Chambers M.D. a Cardiologist who uses guidewires extensively in his practice and experiments with and designs new guidewires, stating he is familiar with the art of guidewires and the medical literature about guidewires and that guidewires containing nickel are in wide use without any reported cases in the medical literature of allergic reactions to the nickel content of the guidewires.

He further states that as an expert in the field he would not look to the stent art to find an alloy for a guidewire to overcome the allergic reaction to nickel content in guidewires since no such problem exists.

Since there is no allergic reaction to the nickel in guidewires as asserted by the Patent Office the obviousness rejection based on the combination of Cornish et al. and Meyer to avoid undue irritation to patients having a sensitivity to nickel should be withdrawn and the claims should be allowed.

The Patent Office rejected the claims as being obvious over Cornish et al. in view of Hermes et al. stating that it would be obvious to modify the wire as disclosed in Cornish et al. to be formed of titanium molybdenum alloy as taught by Hermes et al. because the titanium molybdenum alloy has about three times as much elasticity as other possible alloys and thus helps to avoid unwanted permanent deformation.

Hermes et al is for an implantable filter, which prevents movement of blood clots in a blood vessel. The legs of the filter are deformed to place them in a tube for delivery into the patient. When the filter is withdrawn from the tube it is desired to have the legs expand outward and engage the wall of a blood vessel with hooks to hold the filter in place. The elasticity of the material of the legs is important to expand when taken out of the tube. This elasticity for expanding opposing legs to drive the hooks thereon into the walls of the blood vessel has nothing to do with guidewires and it is not understood why the patent office has cited this art since driving the hooks on legs of a filter into the walls of a blood vessel is totally opposite of the result wanted in a guidewire which is to smoothly pass through tortuous paths in blood vessels. The art cited by the patent office seems to teach away from the applicant's claims.

Therefore the applicant believes that the combination of Cornish et al. and Hermes et al. does not render the claims obvious. The rejection should be withdrawn and the claims should be allowed over the references.